Initial Approval: July 26, 2017
Revised Dates: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Kisqali® (ribociclib)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ribociclib (Kisqali®)
Ribociclib/letrozole (Kisqali Femara Co-Pack)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have a diagnosis of advanced or metastatic breast cancer
- The tumor must be hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative
- Medication must be used in combination with an aromatase inhibitor as initial endocrine-based therapy
- Must be prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient must be postmenopausal
- Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 3 weeks after the last dose
- Patient must not be on a strong CYP3A4 inducer
- Patient must have a baseline QTcF value less than 450 msec

LENGTH OF APPROVAL: 12 months

Notes:

- Recommended dosing is 600 mg once daily for 21 days followed by 7 days off treatment to comprise a complete cycle of 28 days
- When co-administered with letrozole, recommended dose of letrozole is 2.5 mg once daily continuously throughout the 28-day cycle.
- Aromatase inhibitors: Femara (letrozole), Arimidex (anastrozole), Aromasin (exemestane). Clinical trials only evaluated use with letrozole.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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DATE	DATE